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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,108	01/23/2004	David Namey JR.	99-21 D1	7887
30031	7590	07/13/2006	EXAMINER	
MICHAEL W. HAAS, INTELLECTUAL PROPERTY COUNSEL RESPIRONICS, INC. 1010 MURRY RIDGE LANE MURRYSVILLE, PA 15668			BUTLER, PATRICK	
			ART UNIT	PAPER NUMBER
			1732	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/764,108	NAMEY, DAVID
	Examiner	Art Unit
	Patrick Butler	1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 May 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 17-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 May 2006 has been entered.

Response to Amendment

The Applicant's Amendments and Accompanying Remarks, filed 12 April 2006, have been entered and have been carefully considered. No Claims are new, Claim 17 is amended, no Claims are canceled, and Claims 17-24 are pending with Claims 21-24 withdrawn.

Despite these advances, the invention as currently claimed is not found to be patentable for reasons herein below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 17 was amended to include the mask and seal limitation of gas-tight. While the specification does discuss minimizing gas leakage (paragraph [0020]) with a tight seal, it does not teach making the seal become gas-tight as claimed.

Claim Rejections - 35 USC § 103

Claim 17-19 is rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (Admission, page -1- of Spec.) in view of Namey (US Patent No. 5,902,276) and Toffolon (US Patent No. 4,971,051).

With respect to claim 17, prior art (Admission) discloses that two part molded masks are available, which have a mask seal and a mask body, and they are bonded together either mechanically or with an adhesive (see Specification, Paragraph 2).

Admission lacks or does not expressly disclose injection molding these components in a manner such that the second material is injected into the masks mold while the mask body is cooling and incompletely cured to define at least a portion of a mask seal member of the mask, wherein the mask seal member is molecularly bonded to the mask body as a consequence of the second material being injected into the mask mold in this manner.

Namey '276 discloses a solution to the problem of the expensive and time-consuming hand assembly of a two-part unit (mask) formed of a hard plastic core (mask body) and a rubber cover (seal) (see col. 1, lines 29-40). Namey '276 teaches that a two-shot mold (mask mold) is used to facilitate manufacture by having a first injection of

hard plastic (first material to form mask body) and a subsequent over molding of rubber (second material to form seal) tending to form a molecular bond to the underlying plastic (first material) to form a single unit (mask) (see col. 1, lines 56-76). Given that the bond between the two materials is a molecular bond, the seal would be gas-tight at least until the bond is broken.

Namey '276 and Admission are analogous art because they both deal with the technical challenge of attaching a two-part unit of a hard core and rubber cover.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a two shot mold and two shot process taught by Namey '276 to manufacture the mask body and seal in Admission in order to reduce the expense and time required to make the mask (see Namey '276 col. 1, lines 29-40), which solves the common problem of the expensive and time-consuming hand assembly of a two-part unit (mask) and in order to form a permanent and rugged seal.

Admission lacks or does not expressly disclose that the mask's construction consists of a mask body which includes a wall and a rim at an end portion of the wall.

Toffolon teaches that a mask body has a wall (see wall below arrow in Fig. 2) with a rim at an end portion of the wall (see rim at end of wall below arrow in Fig. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Toffolon's mask construction as the shape in the mask and seal interface in Admission in order to provide a wide interface with the seal (see rim and seal interface in Fig. 2 below arrow).

With respect to Claim 18, admitted prior art (Admission), Namey '276, and Toffolon teach injecting a first material, to form a mask body, and a second material, to form a portion of a mask seal member (first flap member), into a mask mold and having the second material injected while the first material is incompletely cured to cause molecular bonding between the two materials as previously described.

Admission and Namey '276 lack or do not expressly disclose a second flap member that generally overlies the first flap member responsive to the mask being in an assembled configuration.

Toffolon does teach a mask (see Ref. 1) adapted to communicate a flow of breathing gas with an airway of a user, wherein the mask seal includes a second flap member (see Ref. 9) that generally overlies the first flap (See Ref. 11) member responsive to the mask being in an assembled configuration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach a second flap member to the mask in the process of making a two part mask taught by Admission in order to avoid skin irritations and abrasions (see Toffolon col. 1, line 42-45).

With respect to Claim 19, the above combination teaches that the flap ring (See Toffolon Ref. 9) (second flap member) is attached mechanically with the option of having two or one seal (interpreted to mean removable/detachable) (see col. 2, lines 16-21).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art (Admission, page -1- of Spec.) in view of Namey (US Patent No. 5,902,276)

and Toffolon (US Patent No. 4,971,051) as applied to claim 17 above, and further in view of Green (US Patent No. 2,664,887).

With respect to Claim 20, Admitted prior art, Namey '276, and Toffolon teach injecting a first material, to form a mask body, and a second material, to form a portion of a mask seal member (first flap member), into a mask mold and having the second material injected while the first material is incompletely cured to cause molecular bonding between the two materials as previously described.

Additionally, Namey '276's method of attaching two objects is to sequentially injection mold parts together. The first material is a hard plastic core (mask body), and the second material is rubber (coupling member)(see col. 1, lines 56-76).

Admission and Namey '276 lack or do not expressly disclose that the piece made by injecting the second material into the mask mold is a coupling member, which is molded to the mask body.

Green teaches a gas mask that uses a rubber (second material) coupling member (See Ref. 9) attached to the mask body (See Ref. 1)(See Col. 2, lines 12-20).

Namey '276 and Green are analogous art because they both deal with the technical challenge of attaching a two-part unit of a hard core and rubber cover.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the rubber coupling member as taught by Green to be injection molded with the mask body using the second material as taught by Namey '276 in the two shot mold and two shot mask molding process taught by Admission, Namey '276, and Toffolon in order to have a better air tight coupling (see Green col. 2,

lines 27-29) and in order to reduce the expense and time required to join the mask and coupling (see Namey '276 col. 1, lines 29-40).

Response to Arguments

Applicant's arguments filed 12 April 2006 have been fully considered but they are not persuasive.

Applicant argues with respect to the 35 USC 103 rejections. Applicant's arguments appear to be on the grounds that:

1) Namey '276 does not provide for a molecular bond along a mask body and seal interface. Therefore, it would not be gas tight.

The Applicant's arguments are addressed as follows:

1) Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection. (The examiner assumes that "Claim 1" referred to in paragraph 5 of the Remarks refers to Claim 17 given that Claim 1 has been canceled by Applicant.)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Butler whose telephone number is (571) 272-8517. The examiner can normally be reached on Mo.-Th. 7:30 a.m. - 5 p.m. and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-

273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PB
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Art Unit 1732

CH
CHRISTINA JOHNSON
PRIMARY EXAMINER
7/10/06